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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,462	02/23/2004	Humberto A. Berra	4221.1000-002	8228
21005 7590 06/22/2010 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133				
EXAMINER				
PELLEGRINO, BRIAN E				
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3738				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,462

Applicant(s)

BERRA ET AL.

Examiner

Brian E. Pellegrino

Art Unit

3738

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-39, 42-48, 51-69 and 71-114 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1/7/10, 2/24/10, 5/6/10
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7-9, 22, 23, 30-39, 61-64, 68, 69, 73, 74, 78, 79, 83, 84, 88, 89, 93, 94 and 98-109.

Continuation of Disposition of Claims: Claims rejected are 1-6, 10-14, 16-21, 24-29, 42-48, 51-60, 65-67, 71, 72, 75-77, 80-82, 85-87, 90-92, 95-97 and 110-114.

DETAILED ACTION

Information Disclosure Statement

Applicant should note that the large number of references in the attached IDS submittals have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Objections

Claims 71,72 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims depend from a canceled claim.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that the longitudinal support is "on one side of a plane bisecting a longitudinal axis of the graft body", was not found in the written

disclosure. This is essential to explain the orientation of the plane because a plane can bisect another axis in a numerous amount of ways, being perpendicular or at numerous different angled bisections etc.

Also the limitation that the graft body "being free of longitudinal support" was not found in the written disclosure. This is essential also because any structure positioned along the length of the graft body that is of a more rigid material can be considered as support structure, i.e. stent structure.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 10-14, 16-21, 24-29, 42-48, 51-60, 65-67, 71, 72, 75-77, 80-82, 85-87, 90-92, 95-97, 110-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 16, 18, 20, 25, 28, recite that the graft body "being free of longitudinal support on the other side of the plane that bisects the longitudinal axis of the graft body that has the longitudinal support member on the first side of the plane" is ambiguous. It is not clear how this is possible when the graft body has stents positioned along its longitudinal axis and extend around the circumference which clearly provide support and thus establish "longitudinal support" along the length. The claims do not establish how the bisection occurs or what defines "longitudinal support" and therefore is indefinite.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5,10,14,18-21,24,25,27,43-45,47,53,65-67,71,72,80-82,85-87,90-92,110-114 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani et al. (EP 1177779) in view of Penn et al. (6183506). Matsutani et al. show (Fig. 1) a vascular device with structural framework having at least two pairs of Z-stents having linear profiles and a longitudinal support member **3** that is on one side of a plane bisecting the longitudinal axis of the device and the other side of the plane is free of the "longitudinal support" as best understood. Matsutani et al. also disclose the stent framework has a graft thereon, paragraph 28. However, Matsutani et al. does not disclose the longitudinal support member being "substantially reverse-mirror symmetrical" with respect to the longitudinal axis. Penn et al. teach (Fig. 4) that a stent support member **370** can be preformed as a "substantially reverse-mirror symmetrical" or S-shape member and such curving imparts greater flexibility, col. 4, lines 2-7. It would have been obvious to one of ordinary skill in the art to use a curved or "substantially reverse-mirror symmetrical" longitudinal support member as taught by Penn et al. in the stent graft of Matsutani et al. such that it permits proper bending and flexibility to shorten without kinking. With respect to claim 2, Matsutani et al. disclose the longitudinal support member is nitinol, paragraph 41. Regarding claims 4,5,111 it can be construed the support member taught by Penn is a "partial" helical shape and "substantially" asymptotic. With respect to claim 14, it can be seen the support member

is shorter than the structural framework, Figs. 1,5. Regarding claim 21, Penn et al. teach that a longitudinal support member need not extend beyond the Z-stents but can be attached to their apices, thus, it would have been obvious to one of ordinary skill in the art to have the support member of Matsutani connected entirely between inner stents, i.e. at the apices as taught by Penn et al. to thus impart greater flexibility. Regarding claims 47,53,55,57 Matsutani disclose the graft body having a diameter as large as the diameter of the vessel to be implanted, paragraph 36. With respect to claims 67,72,82,87,92 Matsutani show (Fig. 6) the stents have a circular cross-sectional shape. Regarding claims 112-114, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a graft having a length of about 20cm long or about 9cm long and the degrees of the orientation of proximal and distal portions of the longitudinal support member having a range between 80-110 degrees or 30-60 degrees respectively, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. With respect to claim 18, it is noted Matsutani et al. disclose the stent graft can use one longitudinal support member, paragraph 41 and is shown (Fig. 1) to only extend to the proximal end of a stent at one end and not its distal end, thus is shorter than the distance between the separation of the distal ends of stents from one another. Thus, it forms a gimbal at least one end.

Claims 6, 26,28,29,46,59,95-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani et al. (EP 1177779) in view of Penn et al. '506 as applied to claim 1 above, and further in view of Robinson et al. (WO 98/23242). Matsutani et al.

as modified by Penn et al. is explained supra. However, Matsutani in view of Penn do not explicitly state the longitudinal support member is independent of the structural framework. Robinson teaches the longitudinal support members can be connected to the graft via sutures and thus is not a permanent affixation to the structural framework and therefore can be interpreted as independent from the framework, page 14, line 12. It would have been obvious to one of ordinary skill in the art to use the longitudinal support member free from the framework as taught by Robinson et al. with the stent graft of Matsutani et al. as modified by Penn et al. such that it permits the graft body to freely conform to the curvature of the vessel.

Claims 11-13, are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani et al. (EP 1177779) in view of Penn et al. '506 as applied to claim 1 above, and further in view of Bolea et al. (6821291). Matsutani as modified with Penn et al. is explained supra. However, Matsutani et al. in view of Penn et al. fail to disclose the longitudinal member has looped or rounded ends at the extremities. Bolea et al. teach (Fig. 22) a stent with a wire member having looped extremities **184**. Bolea et al. also teach that the loops enable an end to be collapsed to remove the stent device, col. 10, lines 31-36. It would have been obvious to one of ordinary skill in the art to use looped ends on a longitudinal wire support member as taught by Bolea et al. and incorporate into the stent graft of Matsutani et al. as modified by Penn et al. to provide the ability to remove the prosthesis if necessary.

Claims 16,17,42,51,75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani et al. (EP 1177779) in view of Penn et al. '506 and

Robinson et al. (WO 98/23242) and Bolea et al. (6821291). Matsutani as modified with Penn et al. is explained supra. However, Matsutani et al. in view of Penn et al. fail to disclose the longitudinal member is connected independent of the structural framework or has a longitudinal extremity curved back upon itself. Robinson et al. is explained above regarding the longitudinal support member being attached to the graft independent of the structural framework. Bolea et al. teach (Fig. 22) a stent with a wire member having looped extremities **184**. Bolea et al. also teach that the loops enable an end to be collapsed to remove the stent device, col. 10, lines 31-36. It would have been obvious to one of ordinary skill in the art to independently attach the longitudinal member as taught by Robinson for the ability to have the graft conform better to the vessel contour and use looped ends on a longitudinal wire support member as taught by Bolea et al. and incorporate into the stent graft of Matsutani et al. as modified by Penn et al. to provide the ability to remove the prosthesis if necessary.

Claims 48,54,56,58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani et al. (EP 1177779) in view of Penn et al. '506 as applied to claims 1,18,20,25 above, and further in view of Hartley et al. (6524335). Matsutani in view of Penn is explained supra. However, Matsutani as modified with Penn fail to disclose a distal most stent with one more apex more than another of stents. Hartley et al. teach (Fig. 2) a stent graft with a distal stent **1** having an apex more than another of the stents. It would have been obvious to one of ordinary skill in the art to use stents with at least one more apex than other stents to better anchor in the vessel as taught by

Hartley et al. and incorporate into the stent graft of Matsutani et al. as modified with Penn et al. to improve the seal of the graft against the vessel wall.

Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani et al. (EP 1177779) in view of Penn et al. '506 and Robinson et al. (WO 98/23242) as applied to claim 28, above, and further in view of Hartley et al. (6524335). Matsutani in view of Penn and Robinson is explained supra. However, Matsutani as modified with Penn and Robinson fail to disclose a distal most stent with one more apex more than another of stents. Hartley et al. teach (Fig. 2) a stent graft with a distal stent 1 having an apex more than another of the stents. It would have been obvious to one of ordinary skill in the art to use stents with at least one more apex than other stents to better anchor in the vessel as taught by Hartley et al. and incorporate into the stent graft of Matsutani et al. as modified with Penn et al. and Robinson to improve the seal of the graft against the vessel wall.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsutani et al. (EP 1177779) in view of Penn et al. '506 and Robinson et al. (WO 98/23242) and Bolea et al. '291 as applied to claim 16, above, and further in view of Hartley et al. (6524335). Matsutani in view of Penn and Robinson and Bolea is explained supra. However, Matsutani as modified with Penn and Robinson and Bolea fail to disclose a distal most stent with one more apex more than another of stents. Hartley et al. teach (Fig. 2) a stent graft with a distal stent 1 having an apex more than another of the stents. It would have been obvious to one of ordinary skill in the art to use stents with at least one more apex than other stents to better anchor in the vessel as

taught by Hartley et al. and incorporate into the stent graft of Matsutani et al. as modified with Penn et al. and Robinson and Bolea to improve the seal of the graft against the vessel wall.

Response to Arguments

Applicant's arguments with respect to claims 1,16,18,20,25,28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738